Artificial heart valve

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An **artificial heart valve** is a device which is implanted in the heart of patients who suffer from valvular diseases in their heart. When one or two of the four heart valves of the heart have a malfunction, the choice is normally to replace the natural valve by an artificial valve. This requires open-heart Surgery.

Valves are integral to the normal physiological functioning of the human heart. Natural heart valves are structures which have evolved a form which meets their functional requirements, which is to induce largely unidirectional flow through themselves. Natural heart valves may become dysfunctional due to a variety of pathological causes. Certain heart valve pathologies may necessitate the complete surgical replacement of the natural heart valves with heart valve prostheses.

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There are two main types of artificial heart valves: the *mechanical* and the *biological valves*.

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- Biological heart valves
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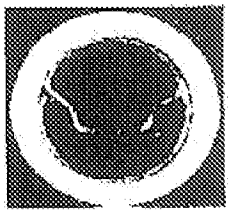
  - Xenograft

Mechanical valves



A mechanical artificial heart valve with a pivoting disc.

Mechanical heart valves are prosthetics designed to replicate the function of the natural valves of the human heart. The human heart contains four valves: tricuspid valve, pulmonic valve, mitral valve and aortic valve. Their main purpose is to maintain unimpeded forward flow through the heart and from the heart into the major blood vessels connected to the heart, the pulmonary artery and the aorta. As a result of a number of disease processes, both acquired and congenital, any one of the four heart valves may malfunction and result in either stenosis (impeded forward flow) and/or backward flow (regurgitation). Either process burdens the heart and may lead to serious problems including heart failure. A mechanical heart valve is intended to replace a diseased heart valve with its prosthetic equivalent.

There are two basic types of valves that can be used for aortic valve replacement, mechanical and tissue valves. Modern mechanical valves can last indefinitely (the equivalent of over 50,000 years in an accelerated valve wear tester). However, current mechanical heart valves all require lifelong treatment with a blood thinner, e.g. warfarin, which requires monthly blood tests to monitor. This process of thinning the blood is called anticoagulation. Tissue heart valves, in contrast, do not require the use of anticoagulant drugs due to the improved blood flow dynamics resulting in less red cell damage and hence less clot formation. Their main weakness however, is their limited lifespan. Traditional tissue valves, made of pig heart valves, will last on average 15 years before they require replacement. (Studies as of November 2006 suggest that they may last longer in recipients under 50, refuting previous understanding)

Types of MHV's

There are three major types of mechanical valves - *caged-ball*, *tilting-disk* and *bileaflet* - with many modifications on these designs.

The first artificial heart valve was the **caged-ball** which utilizes a metal cage to house a metal ball. When blood pressure in the chamber of the heart exceeds that of the pressure on the outside of the chamber the ball is pushed against the cage and allows blood to flow. At the completion of the heart's contraction, the pressure inside the chamber drops and is lower than beyong the valve, so the ball moves back against the base of the valve forming a seal. In 1952, Dr. Charles Hufnagel implanted caged-ball heart valves in ten patients (six survived the operation), marking the first long-term success in prosthetic heart valves. A similar valve was invented by Miles "Lowell" Edwards and Albert Starr in 1960 (commonly referred to as the Starr-Edwards Silastic Ball Valve). The first human implant was on Sept 21, 1960. Currently, the only caged-ball design approved for use in the US is the Starr-Edwards valve. It consists of a silicone ball enclosed in a cage formed by wires originating from the valve housing. Caged ball valves have a high tendency to forming blood clots, so the patient must have a high degree of anti-coagulation, usually with a target INR of 4.0–4.9.

Soon after came **tilting-disc** valves, which have a single circular occluder controlled by a metal strut. They are made of a metal ring covered by a tissue, into which the suture threads are stitched in order to hold the valve in place. The metal ring holds, by means of two metal supports, a disc which opens and closes as the heart pumps blood through the valve. The disc is usually made of an extremely hard carbon material (pyrolytic carbon), in order to allow the valve to function for years without wearing out. The

Medtronic-Hall model is the most common tilting-disc design in the US. In some models of mechanical valves, the disc is divided into two parts, which open and close as a door.

These *bileaflet* valves have the advantage that they have a greater effective opening area (2.4-3.2 square cm c.f. 1.5-2.1 for the single-leaflet valves). Also, they are the least thrombogenic of the artificial valves.

St. Jude Medical is the leader in **bileaflet valves**, which consist of two semicircular leaflets that rotate about struts attached to the valve housing. This design was introduced in 1979 and while they take care of some of the issues that were seen in the other models, bileaflets are vulnerable to backflow and so it cannot be considered as ideal. Bileaflet valves do, however, provide much more natural blood flow than caged-ball or tilting-disc implants. One of the main advantages of these valves is that they are well tolerated by the body. Only a small amount of blood thinner is needed to be taken by the patient each day in order to prevent clotting of the blood when flowing through the valve.

Mechanical heart valves are today very reliable and allow the patient to live a normal life. Most mechanical valves last for at least 20 to 30 years.

Durability

Mechanical heart valves are considered to be extremely durable in comparison to their bioprosthetic counterparts. The struts and occluders are made out of either pyrolytic carbon or titanium coated with pyrolytic carbon, and the sewing ring cuff is Teflon, polyester or dacron. The major load arises from transvalvular pressure generated at and after valve closure, and in cases where structural failure does happen, it is usually as a result of occluder impact on the components.

Impact wear and friction wear dictate the loss of material in MHV's. Impact wear usually occurs in the hinge regions of bileaflets, between the occluder and ring in tilting-discs, and between the ball and cage in caged-ball valves. Friction wear occurs between the occluder and strut in tilting-discs, and between the leaflet pivots and hinge cavities in bileaflets.

MHV's made out of metal are also susceptible to fatigue failure owing to the polycrystalline characteristic of metals, but this is not an issue with pyrolytic carbon MHV's because this material is not crystalline in nature.

Cavitation should also be considered when studying degradation of MHV's.

Fluid mechanics

Many of the complications associated with MHV's can be explained through fluid mechanics. For example, thrombus formation is a debilitating side effect of high shear stresses created by the design of the valves. An ideal heart valve from an engineering perspective would produce minimal pressure drops, have small regurgitation volumes, minimize turbulence, reduce prevalence of high stresses, and not create flow separations in the vicinity of the valve.

One measure of the quality of a valve is the effective orifice area (EOA), which can be calculated as follows:

$$EOA(\mathrm{cm}^2) \quad \frac{Q_{rms}}{51.6\sqrt{\Delta p}}$$

where Q_{rms} is the root mean square systolic/diastolic flow rate (cm^3/s) and Δp is the mean systolic/diastolic pressure drop (mmHg). This is a measure of how much the prosthesis impedes blood flow through the valve. A higher EOA corresponds to a smaller energy loss. The performance index (PI) normalizes the EOA by valve size and is a size-independent measure of the valve's resistance characteristics. Bileaflet valves typically have higher PI's than tilted-disc models, which in turn have higher PI's than caged-ball models.

As blood flows through a prosthetic heart valve, a sudden pressure drop occurs across the valve due to the reduction in cross-sectional area within the valve housing. This can be quantified through the continuity equation and Bernoulli's equation:

$$A_1 V_1 = A_2 V_2$$

$$P_1 + \frac{1}{2}\rho_1 V_1^2 = P_2 + \frac{1}{2}\rho_2 V_2^2$$

where A represents the cross-sectional area, P is pressure, $?$ is density, and V is the velocity. As cross-sectional area decreases in the valve, velocity increases and pressure drops as a result. This effect is more dramatic in caged-ball valves than in tilting-disc and bileaflet valves. A larger systolic pressure is required to drive flow forward in order to compensate for a large pressure drop, so it should be minimized.

Regurgitation is the sum of retrograde flow during the closing motion of the valve and leakage flow after closure. It is directly proportional to valve size and is also dependent on valve type. Typically, caged-ball valves have a low amount of regurgitation as there is very little leakage. Tilting-disc and bileaflet valves are comparable, with the bileaflet valves have a slightly larger regurgitation volume. Bioprosthetics prevail over MHV's in this case, as they have virtually no regurgitation volume.

Turbulence and high shear stresses are also major issues with MHV's, as they can fracture the valve housing or components, or induce blood damage. A large flow gradient can lead to these factors, so flow separation and stagnation should be as small as possible. High stresses are created at the edges of the annular jet in caged-ball valves, in narrow regions at the edges of the major orifice jet in tilting-disc valves, and in regions immediately distal to the valve leaflets in bileaflet valves. The implications of blood damage from these stresses are discussed in the next section.

The cavitation phenomenon can also be described using fluid mechanics. This can result from pressure oscillations, flow deceleration, tip cortices, streamline contraction, and squeeze jets [4]. This last cause is the most contributive factor to cavitation. The squeeze jets are formed when the valve is closing and the blood between the occluder and valve housing is "squeezed" out to create a high-speed jet. This in turn creates intense vortices with very low pressures that can lead to cavitation.

Blood damage

One of the major drawbacks of mechanical heart valves is that patients with these implants require

consistent anti-coagulation therapy. Clots formed by red blood cell (RBC) and platelet damage can block up blood vessels and lead to very serious consequences. Clotting occurs in one of three basic pathways: tissue factor exposure, platelet activation, or contact activation by foreign materials, and in three steps: initiation, amplification, and propagation.

In the tissue factor exposure path, initiation begins when cells are ruptured and expose tissue factor (TF). Plasma Factor (f) VII binds to TF and sets off a chain reaction which activates fXa and fVa which bind to each other to produce thrombin which in turn activates platelets and fVIII. The platelets activate by binding to the damaged tissue in the initiation phase, and fibrin stabilizes the clot during the propagation phase.

The platelet activation pathway is triggered when stresses reach a level above 6 to 8 Pa (60–80 dyn/cm^2). The steps involved with this are less clearly understood, but initiation begins with the binding of vWF from the plasma to GPIb on the platelet. This is followed by a large influx of Ca^{2+} ions, which activates the platelets. GPIIb-IIIa facilitates platelet-platelet adhesion during amplification. The propagation step is still under study.

Contact activation begins when fXII binds to a negatively charged surface. This in turn activates prekallikrein (PK) and high-molecular-weight kininogen (HK). Eventually, HKa-PK and HKa-fXI complexes form on the surface. In amplification, Hka-FXIa complexes activate fIX to fIXa, which in turn forms thrombin and platelets. Proteins buildup on the surface and facilitate platelet adhesion and tissue growth in the propagation stage.

All MHV models are vulnerable to thrombus formation due to high shear stress, stagnation, and flow separation. The caged-ball designs experience high stresses at the walls that can damage cells, as well as flow separation due to high-velocity reverse flow surrounded by stagnant flow. Tilting-disc valves have flow separation behind the valve struts and disc as a result of a combination of high velocity and stagnant flows. The bileaflet models have high stresses during forward and leakage flows as well as adjacent stagnant flow in the hinge area. As it turns out, the hinge area is the most critical part of bileaflets and is where the thrombus formation is usually prevalent.

In general, blood damage affects valves in both the mitral and aortic positions. High stresses during leakage flow in aortal valves result from higher transvalvular pressures, and high stresses occur during forward flow for mitral valves. Valvular thrombosis is most common in mitral prosthetics. The caged-ball model is better than the other two models in terms of controlling this problem, because it is at a lower risk for thrombosis and it is gradual when it does happen. The bileaflet is more adaptable to this problem than the tilting-disc model because if one leaflet stops working, the other can still function. However, if the hinge is blocked, both leaflets will stop functioning.

Because all models experience high stresses, patients with mechanical heart valve implants require anti-coagulation therapy. Bioprosthetics are less prone to develop blood clotting, but the trade-off concerning durability generally favors their use in patients older than age 55.

Mechanical heart valves can also cause hemolytic anemia with hemolysis of the red blood cells as they pass through the valve.

Biological valves

Biological valves are valves of animals, like pigs, which undergo several chemical procedures in order to make them suitable for implantation in the human heart. The porcine (or pig) heart is most similar to the human heart, and therefore represents the best anatomical fit for replacement. Implantation of a porcine valve is a type of Xenotransplantation, or Xenograft, which means a transplant from one species (in this case a pig) to another. There are some risks associated with a Xenograft such as the human bodies tendency to reject foreign material. Medication can be used to retard this effect, but is not always successful.

Another type of biological valve utilizes biological tissue to make leaflets that are sewn into a metal frame. This tissue is typically harvested from the *Pericardial Sac* of either Bovine (cows) or Equine (horses). The pericardial sac is particularly well suited for a valve leaflet due to its extremely durable physical properties. This type of biological valve is extremely effective means of valve replacement. The tissue is sterilized so that the biological markers are removed eliminating a response from the host's immune system. The leaflets are flexible and durable and do not require the patient to take blood thinners for the rest of their life.

The most used heart valves in the US and EU are those utilizing tissue leaflets. Mechanical valves are more commonly used in Asia and Latin America. The following companies manufacture artificial heart valves: Medtronic, Edwards Lifesciences, and St. Jude.

Functional requirements of heart valve prostheses

The functioning of natural heart valves is characterised by many advantages:

- Minimal regurgitation - This means that the amount of blood lost upstream as the valve closes is small. For example, closure regurgitation through the mitral valve would result in some blood loss from the left ventricle to the left atrium as the mitral valve closes. Some degree of valvular regurgitation is inevitable and natural (Fixme: Give indicative value). However, several heart valve pathologies (e.g. rheumatic endocarditis) may lead to clinically significant valvular regurgitation. A desirable characteristic of heart valve prostheses is that regurgitation is minimal over the full range of physiological heart function (i.e. complete functional envelope of cardiac output vs. heart rate).
- Minimal transvalvular pressure gradient - Whenever a fluid flows through a restriction, such as a valve, a pressure gradient arises over the restriction. This pressure gradient is a result of the increased resistance to flow through the restriction. Natural heart valves have a low transvalvular pressure gradient as they present little obstruction to the flow through themselves (Fixme: Give indicative value). A desirable characteristic of heart valve prostheses is that their transvalvular pressure gradient is as small as possible.
- Non-thrombogenic - As natural heart valves are lined with an endothelium continuous with the endothelium lining the heart chambers they are not normally thrombogenic. This is important as should thrombus form on the heart valve leaflets and become seeded with bacteria, so called "bacterial vegetations" will form. Such vegetations are difficult for the body to deal with as the normal physiological defense mechanisms are not present within the valve leaflets because they are avascular and largely composed of connective tissue (Fixme: Create article discussing the pathgonesis of leaflet bacterial vegetations.). Should bacterial vegetations form on the valve leaflets they may continually seed bacteria into the arterial tree which may lead to bacteremia or septicaemia. Portions of the vegetation may also break off forming septic emboli. Septic emboli can lodge anywhere in the arterial tree (e.g. brain, bowel, lungs) causing local infectious foci.

Even dislodged fragments from non-infectious vegetations (Fixme: Is this the correct terminology?) can be hazardous as they can lodge in, and block, downstream arteries (e.g. coronary arteries leading to myocardial infarction, cerebral arteries leading to stroke). A desirable characteristic of heart valve prostheses is that they are non or minimally thrombogenic.

- Self-repairing - Although of limited extent compared to well vascularised tissue (e.g. muscle), the valve leaflets do retain some capacity for repair due to the presence of regenerative cells (e.g. fibroblasts) in the connective tissue from which the leaflets are composed. As the human heart beats approximately 3.4×10^{12} times during a typical human lifespan this limited but nevertheless present repair capacity is critically important. No heart valve prostheses can currently self-repair but replacement tissues grown using stem cell technology may eventually offer such capabilities. (State that they wear).
- Rapid dynamic response - STD

Design challenges of heart valve prostheses

- Thrombogenesis / haemocompatibility
  - Mechanisms:
    - Forward and backward flow shear
    - Static leakage shear
    - Presence of foreign material (i.e. intrinsic coagulation cascade)
    - Cellular masceration
- Valve-tissue interaction
- Wear
- Blockage
- Getting stuck
- Dynamic responsiveness
- Failure safety
- Valve orifice to anatomical orifice ratio
- Trans-valvular pressure gradient
- Minimal leakages

Typical configuration of a heart valve prosthesis

- Anchor
- Leaflets

MHV manufactures

Companies that manufacture MHVs include:

Edwards Lifescience (formerly Baxter-Edwards Critical Care) (http://www.edwards.com/)

TTK Chitra (http://ttkchitraheartvalve.com/)

St. Jude (http://www.sjm.com/devices/devicetype.aspx?location=in&type=18)

Medtronic (http://www.ctsnet.org/medtronic/product/609)

CarboMedics (http://www.carbomedics.com/professional_products_sunitral.asp?from=us)

External links

- Page describing types of heart valve replacements (http://www.mayoclinic.org/heart-valve-surgery/treatment.html)

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